AF/ CPW 1614

PATENT

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May 3, 2005
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Jason Anover

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Thomas D. Madden et al.
Application No.	:	09/896,811
Filed	:	June 29, 2001
For	:	LIPOSOMAL CAMPTOTHECINS AND USES THEREOF

Examiner	:	Frederick F. Krass
Art Unit	:	1614
Docket No.	:	480208.407
Date	:	May 3, 2005

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents:

In accordance with 37 CFR 1.56 and 1.97 through 1.98, applicants wish to make known to the U.S. Patent and Trademark Office the references set forth on the attached Form PTO-1449. Copies of the cited U.S. patents and published patent applications are not required and accordingly have not been provided. Copies of all other cited references are enclosed. As to any reference cited, applicants do not admit that it is "prior art" under 35 U.S.C. §§ 102 or 103, and specifically reserve the right to traverse or antedate any such reference, as by a showing under 37 CFR 1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with applicants' duty to disclose all information they

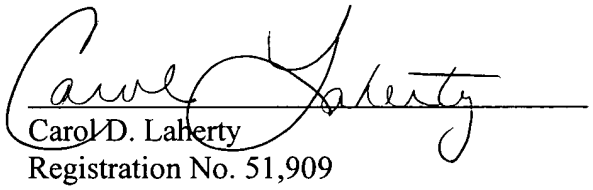
are aware of which is believed relevant to the examination of the above-identified application, applicants believe that their invention is patentable.

Please acknowledge receipt of this Supplemental Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Applicants believe this Supplemental Information Disclosure Statement has been timely filed, however, the Director is authorized to charge any fee due by way of this Information Disclosure Statement to our Deposit Account No. 19-1090.

Respectfully submitted,

Seed Intellectual Property Law Group PLLC



Carol D. Laherty
Registration No. 51,909

Enclosures:

Postcard
Form PTO-1449
Cited References (124)

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586412

TRANSMITTAL FORM

(To be used for all correspondence after initial filing)

Application Number	09/896,811
Filing Date	June 29, 2001
First Named Inventor	Thomas D. Madden
Art Unit	1614
Examiner Name	Frederick F. Krass
Attorney Docket No.	480208.407

ENCLOSURES (*check all that apply*)

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Response
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement; Form PTO-1449
- ☒ Cited References
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts under 37 C.F.R. 1.52 or 1.53
- ☐ Response to Missing Parts/Incomplete Application
- ☐ Drawing(s)
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- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation, Change of Correspondence Address
- ☐ Declaration
- ☐ Statement under 37 CFR 3.73(b)
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- ☐ Appeal Communication to Board of Appeals and Interferences
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Printed Name	Carol D. Laherty		
Date	May 3, 2005	Reg. No.	51,909

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FORM PTO-1449 (REV.7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 480208.407	APPLICATION NO. 09/896,811
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		APPLICANTS Thomas D. Madden et al.	
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U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES	TRANSLATION NO
	AB					

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	AC		Abraham, S. A., K. Edwards, et al. "An evaluation of transmembrane ion gradient-mediated encapsulation of topotecan within liposomes." *J Control Release 96*(3): 449-61, 2004.
	AD		Apostolidou, E., G. Garcia-Manero, et al. "Phase I Study of OSI-211, a Novel Liposomal Topoisomerase 1 (Topo 1) Inhibitor, in Patients with Refractory Leukemia." *Blood*, 2002. Abstract #4575.
	AE		Biloti, D. N., A. Santana Maria Helena, et al. "Lipid membrane with low proton permeability." *Biochim Biophys Acta 1611*(1-2): 1-4, 2003.
	AF		Bom, D., D. P. Curran, et al. "The novel silatecan 7-tert-butyldimethylsilyl-10-hydroxycamptothecin displays high lipophilicity, improved human blood stability, and potent anticancer activity." *J Med Chem 43*(21): 3970-80, 2000.
	AG		Bom, D., D. P. Curran, et al. "The highly lipophilic DNA topoisomerase I inhibitor DB-67 displays elevated lactone levels in human blood and potent anticancer activity." *J Control Release 74*(1-3): 325-33, 2001.
	AH		Burke, T. G. and D. Bom, "Camptothecin design and delivery approaches for elevating anti-topoisomerase I activities in vivo." *Ann N Y Acad Sci 922*: 36-45, 2000.
	AI		Burke, T. G. and X. Gao "Stabilization of topotecan in low pH liposomes composed of distearoylphosphatidylcholine." *J Pharm Sci 83*(7): 967-9, July 1994.
	AJ		Burke, T. G., E. Staubus Alfred, et al. "Liposomal stabilization of Camptothecin lactone ring." *J Am Chem Soc 114*:8318-8319, 1992.
	AK		Burke, T. G., Z. Mi, et al. "Liposomal stabilization of camptothecins." *Proc Amer Assoc Cancer Res. 35*:416, March 1994. Abstract #2479
	AL		Chou, T.-H., S.-C. Chen, et al. "Effect of composition on the stability of liposomal irinotecan prepared by a pH gradient method." *Journal of Bioscience and Bioengineering. 95*(4):405-408, 2003
	AM		Chow, D. S. L., G. Chen, et al. "Liposomal camptothecin and 9-nitro-camptothecin: Formulation, pharmacokinetics and preclinical anti-tumor activity." *Proceedings of the Controlled Release Society,* pp. 919-920, 1997.

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	BA						

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	BB					

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	BC		Chow, D. S., L. Gong, et al. "Modified lactone/carboxylate salt equilibria in vivo by liposomal delivery of 9-nitro-camptothecin." *Ann N Y Acad Sci 922*:164-74, 2000.
	BD		Clements, M. K., C. B. Jones, et al. "Antiangiogenic potential of camptothecin and topotecan." *Cancer Chemother Pharmacol 44*(5): 411-6, 1999.
	BE		Clements, M. K., S. Wasi, et al. "Camptothecin exhibits selective cytotoxicity towards human breast carcinoma as compared to normal bovine endothelial cells in vitro." *Anticancer Drugs 7*(8): 851-7, 1996.
	BF		Colbern, G. T., D. J. Dykes, et al. "Encapsulation of the topoisomerase I inhibitor GL147211C in pegylated (STEALTH) liposomes: pharmacokinetics and antitumor activity in HT29 colon tumor xenografts." *Clin Cancer Res 4*(12): 3077-82, December 1998.
	BG		Daoud, S. S., M. I. Fetouh, et al. "Antitumor effect of liposome-incorporated camptothecin in human malignant xenografts." *Anticancer Drugs 6*(1): 83-93, 1995.
	BH		Dunton, C. J. "New options for the treatment of advanced ovarian cancer." *Semin Oncol 24(1 Suppl 5)*:S5-2-S5-11, February 1997.
	BI		El-Kareh, A. W. and T. W. Secomb "Theoretical models for drug delivery to solid tumors." *Crit Rev Biomed Eng 25*(6): 503-571, 1997.
	BJ		Emerson, D. L. "Liposomal delivery of camptothecins." *Pharmaceutical Science and Technology Today 3*(6): 205-209, June 2000.
	BK		Emerson, D. L., N. Amirgahari, et al. "NX-211, a liposomal formulation of lurtotecan demonstrates enhanced pharmacokinetic and antitumor activity." *Proc Amer Assoc Cancer Res. 39*: 278, March 1998. Abstract #1897.
	BL		Emerson, D. L., R. Bendele, et al. "Antitumor efficacy, pharmacokinetics, and biodistribution of NX 211: a low-clearance liposomal formulation of lurtotecan." *Clin Cancer Res 6*(7): 2903-12, July 2000.
	BM		Emerson, D., A. Gray, et al. "The topoisomerase I inhibitor, NX211 demonstrates significant in vivo activity against human acute myeloid leukemia (AML) engrafted in SCID mice." *Blood*, 1999. Abstract #4223.

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	CA						

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	CB					

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	CC		Erickson-Miller, C. L., R. D. May, et al. "Differential toxicity of camptothecin, topotecan and 9-aminocamptothecin to human, canine, and murine myeloid progenitors (CFU-GM) in vitro." *Cancer Chemother Pharmacol 39*(5): 467-72, 1997.
	CD		Garcia-Carbonero, R. and J.G. Supko "Current perspectives on the clinical experience, pharmacology, and continued development of the camptothecins." *Clin Cancer Res 8*(3): 641-661, March 2002.
	CE		Gelmon, K., H. Hirte, et al. "A phase 1 study of OSI-211 given as an intravenous infusion days 1, 2, and 3 every three weeks in patients with solid cancers." *Invest New Drugs 22*(3): 263-75, 2004.
	CF		Giles, F. J., M. S. Tallman, et al. "Phase I and pharmacokinetic study of a low-clearance, unilamellar liposomal formulation of lurtotecan, a topoisomerase 1 inhibitor, in patients with advanced leukemia." *Cancer 100*(7): 1449-58, April 2004.
	CG		Giles, F., M. Tallman, et al. "Phase I and pharmacokinetic study of OSI-211, a liposomal formulation of lurtotecan, a topoisomerase 1 inhibitor, in patients with advanced leukemia." *Blood*, p. 2516, 2003. Abstract #4732.
	CH		Guo, W., A. Ahmad, et al. "Determination by liquid chromatography with fluorescence detection of total 7-ethyl-10-hydroxy-camptothecin (SN-38) in beagle dog plasma after intravenous administration of liposome-based SN-38 (LE-SN38)." *J Chromatogr B 791*(1-2): 85-92, 2003.
	CI		Hatefi, A. and B. Amsden "Camptothecin delivery methods." *Pharm Res 19*(10):1389-1399, October 2002.
	CJ		Khan, S., A. Ahmad, et al. "A sensitive and rapid liquid chromatography tandem mass spectrometry method for quantitative determination of 7-ethyl-10-hydroxycamptothecin (SN-38) in human plasma containing liposome-based SN-38 (LE-SN38)." *Biomedical chromatography - BMC 17*(8): 493-9, 2003.

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	DB					

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	DC		Knight, V., E. S. Kleinerman, et al. "9-Nitrocamptothecin liposome aerosol treatment of human cancer subcutaneous xenografts and pulmonary cancer metastases in mice." *Ann N Y Acad Sci 922*: 151-63, 2000.
	DD		Knight, V., N. Koshkina, et al. "Anti-cancer activity of 9-nitrocamptothecin liposome aerosol in mice." *Trans Am Clin Climatol Assoc 111*: 135-45, 2000.
	DE		Knight, V., N. V. Koshkina, et al. "Anticancer effect of 9-nitrocamptothecin liposome aerosol on human cancer xenografts in nude mice." *Cancer Chemother Pharmacol 44*(3): 177-86, 1999.
	DF		Koshkina, N. V., B. E. Gilbert, et al. "Distribution of camptothecin after delivery as a liposome aerosol or following intramuscular injection in mice." *Cancer Chemother Pharmacol 44*(3): 187-92, 1999.
	DG		Koshkina, N. V., E. S. Kleinerman, et al. "9-Nitrocamptothecin liposome aerosol treatment of melanoma and osteosarcoma lung metastases in mice." *Clin Cancer Res 6*(7): 2876-80, 2000.
	DH		Koshkina, N. V., V. Knight, et al. "Improved respiratory delivery of the anticancer drugs, camptothecin and paclitaxel, with 5% CO2-enriched air: pharmacokinetic studies." *Cancer Chemother Pharmacol 47*(5): 451-6, 2001.
	DI		Lei, S., P.-Y. Chien, et al. "Enhanced therapeutic efficacy of a novel liposome-based formulation of SN-38 against human tumor models in SCID mice." *Anticancer Drugs 15*(8): 773-8, 2004.
	DJ		Liu, J. J., R. L. Hong, et al. "Simple and efficient liposomal encapsulation of topotecan by ammonium sulfate gradient: stability, pharmacokinetic and therapeutic evaluation." *Anticancer Drugs 13*(7): 709-17, 2002.
	DK		Liu, X., B. C. Lynn, et al. "A versatile prodrug approach for liposomal core-loading of water-insoluble camptothecin anticancer drugs." *J Am Chem Soc 124*(26): 7650-1, 2002.

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	EB					

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	EC		Loos, W. J., D. Kehrer, et al. "Liposomal lurtotecan (NX211): determination of total drug levels in human plasma and urine by reversed-phase high-performance liquid chromatography." *J Chromatogr B 738*(1): 155-63, 2000.
	ED		Loos, W. J., J. Verweij, et al. "Structural identification and biological activity of 7-methyl-10,11-ethylenedioxy-20(S)-camptothecin, a photodegradant of lurtotecan." *Clin Cancer Res 8*(3): 856-62, March 2002.
	EE		Lundberg, B. B. "Biologically active camptothecin derivatives for incorporation into liposome bilayers and lipid emulsions." *Anticancer Drug Des 13*(5): 453-61, 1998.
	EF		Luo, J. D., Z. Q. Ma, et al. "[Studies on polyphase liposome of camptothecin, PL-CSA]." *Yao xue xue bao = Acta pharmaceutica Sinica 19*(1): 63-8,1984.
	EG		Lynam, E., D. J. Landfair, et al. "Camptothecin analogue efficacy in vitro: Effect of liposomal encapsulation of GI147211C (NX211)." *Drug Delivery: Journal of Delivery and Targeting of Therapeutic Agents 6*:51-62, 1999.
	EH		MacKenzie, M. J., H. W. Hirte, et al. "A phase I study of OSI-211 and cisplatin as intravenous infusions given on days 1, 2 and 3 every 3 weeks in patients with solid cancers." *Ann Oncol 15*(4): 665-70, 2004.
	EI		Maliepaard, M., M. A. Van Gastelen, et al. "Circumvention of breast cancer resistance protein (BCRP)-mediated resistance to camptothecins in vitro using non-substrate drugs or the BCRP inhibitor GF120918." *Clin Cancer Res 7*(4): 935-941, April 2001.
	EJ		Meerum, T. J. M., J. H. M. Schellens, et al. "Clinical pharmacology of anticancer agents in relation to formulations and administration routes." *Cancer Treat Rev 25*(2): 83-101, 1999.
	EK		Messerer, C. L., E. C. Ramsay, et al. "Liposomal irinotecan: formulation development and therapeutic assessment in murine xenograft models of colorectal cancer." *Clin Cancer Res 10*(19): 6638-49, October 2004.
	EL		Mi, Z. and T. G. Burke "Differential interactions of camptothecin lactone and carboxylate forms with human blood components." *Biochemistry 33*(34): 10325-36, 1994.

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	FB					

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	FC		Proulx, M. E., A. Desormeaux, et al. "Treatment of visceral leishmaniasis with sterically stabilized liposomes containing camptothecin." *Antimicrob Agents Chemother 45*(9): 2623-7, 2001.
	FD		Proulx, M. E., J. F. Marquis, et al. "Incorporation of campthothecin into liposomes: A new approach for the treatment of leishmaniasis." *Abstracts of the 39th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy*, San Francisco, 1999. Abstract 1856.
	FE		Sadzuka, Y. "Effective prodrug liposome and conversion to active metabolite." *Curr Drug Metab 1*(1): 31-48, 2000.
	FF		Sadzuka, Y., S. Hirotsu, et al. "The study of polyethyleneglycol-coated liposomes containing CPT-11." *J Liposome Res.7*(2&3): 241-260, 1997.
	FG		Sadzuka, Y., S. Hirotsu, et al. "Effect of liposomalization on the antitumor activity, side-effects and tissue distribution of CPT-11." *Cancer Lett 127*(1-2): 99-106, 1998.
	FH		Sadzuka, Y., S. Hirotsu, et al. "Effective irinotecan (CPT-11)-containing liposomes: intraliposomal conversion to the active metabolite SN-38." *Jpn J Cancer Res 90*(2): 226-32, February 1999.
	FI		Seiden, M. V., F. Muggia, et al. "A phase II study of liposomal lurtotecan (OSI-211) in patients with topotecan resistant ovarian cancer." *Gynecol Oncol 93*(1): 229-32, 2004.
	FJ		Stano, P., S. Bufali, et al. "Novel camptothecin analogue (gimatecan)-containing liposomes prepared by the ethanol injection method." *J Liposome Res 14*(1-2): 87-109, 2004.
	FK		Subramanian, D. and M. T. Muller "Liposomal encapsulation increases the activity of the topoisomerase I inhibitor topotecan." *Oncol Res 7*(9): 461-9, 1995.
	FL		Tardi, P., E. Choice, et al. "Liposomal encapsulation of topotecan enhances anticancer efficacy in murine and human xenograft models." *Cancer Res 60*(13): 3389-93, July 2000.
	FM		Tomkinson, B. E., E. Brown, et al. "In vivo evaluation of NX 211 in combination with cisplatin, 5-FU, and paclitaxel." *Proc Amer Assoc Cancer Res. 41*:144, March 2000. Abstract #917.

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	GB					

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	GC		Tomkinson, B., R. Bendele, et al. "OSI-211, a novel liposomal topoisomerase I inhibitor, is active in SCID mouse models of human AML and ALL." *Leukemia Research 27*(11): 1039-50, 2003.
	GD		Verschraegen, C. F., B. E. Gilbert, et al. "Feasibility, phase I, and pharmacological study of aerosolized liposomal 9-nitro-20(S)-camptothecin in patients with advanced malignancies in the lungs." *Ann N Y Acad Sci 922*: 352-4, 2000.
	GE		Verschraegen, C. F., B. E. Gilbert, et al. "Clinical evaluation of the delivery and safety of aerosolized liposomal 9-nitro-20(s)-camptothecin in patients with advanced pulmonary malignancies." *Clin Cancer Res 10*(7): 2319-26, April 2004.
	GF		Verschraegen, C. F., K. Jaeckle, et al. "Alternative administration of camptothecin analogues." Ann N Y Acad Sci 922: 237-46, 2000. Abstract only
	GG		Zhang, J. A., T. Xuan, et al. "Development and characterization of a novel liposome-based formulation of SN-38." *Int J Pharm 270*(1-2): 93-107, 2004.
	GH		Zhang, Q. M., X. Q. Gu, et al. "[A method for determining the encapsulation ratio of camptothecin in polyphase liposome and studies on its leakage property]." *Yao xue xue bao = Acta Pharmaceutica Sinica 22*(12): 918-22, 1987.
	GI		Zufia, L., A. Aldaz, et al. "Separation methods for camptothecin and related compounds." *J Chromatogr B 764(*1-2): 141-159, 2001.
	GJ		Zunino, F., S. Dallavalle, et al. "Current status and perspectives in the development of camptothecins." *Curr Pharm Des 8*(27): 2505-2520, 2002.
	GK		Desjardins, J. P., E. A. Abbott, et al. (2001). "Biodistribution of NX211, liposomal lurtotecan, in tumor-bearing mice." *Anticancer Drugs 12*(3): 235-45, March 2001.
	GL		Begu, S., C. Tourne-Peteilh, et al. "Spectrofluorimetry study of interaction of camptothecin with liposomal bilayer." *Luminescence 15*:78-79, 2000.
	GM		Bell, C. B., D. J. Landfair, et al. "Topoisomerase I (TOPO-1) modulation by liposomal GI147211 (NX211)." *Proc Amer Assoc Cancer Res 41*, p. 773, March 2000. Abstract #4915.

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	HA						

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	HF		Burke, T. G., S. Gao Xiang, et al. "Liposomal stabilization of the lactone ring of camptothecin anticancer drugs." *Pharm Res 10*(10):S-220, October 1993. Abstract # PDD 7483.
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FORM PTO-1449 (REV.7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 480208.407	APPLICATION NO. 09/896,811
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		APPLICANTS Thomas D. Madden et al.	
		FILING DATE June 29, 2001	GROUP ART UNIT 1614

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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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	LA						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES	TRANSLATION NO
	LB					

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	LC		Sarkar, A., N. Kamath, et al. "Toxicity evaluation of a liposome-based formulation of SN38 in mice." *Toxicol Sci 72*(S-1):83, March 2003. Abstract #403.
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